MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

# Overview Massachusetts BioPharma Industry and BioReady Communities

2013

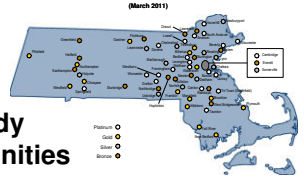
MassBio
Massachusetts Biotechnology Council

MassBio
Massachusetts Biotechnology Council

*Founded in 1985*

Our goal is the success of our member organizations.





BioReady Communities Campaign

Shire

RainDance Technologies

Savings from 20 % on everything from lab gases, lab equipment, supplies…

State & Federal Policy

Purchasing Consortium

Economic Development

MassBio

Networking & Visibility

MassBioEd Foundation

BioTeach

MLSEC

110+ member meetings, 4,000 attendees

Annual Events

Professional Development

4th Annual International Partnering Conference
BioPharm America 2011

Innovation Services
MassConnect
Innovation Exchange
- Investment
- Mentoring
- Partnering

MassBioEd Courses, MassBio Committee Meetings

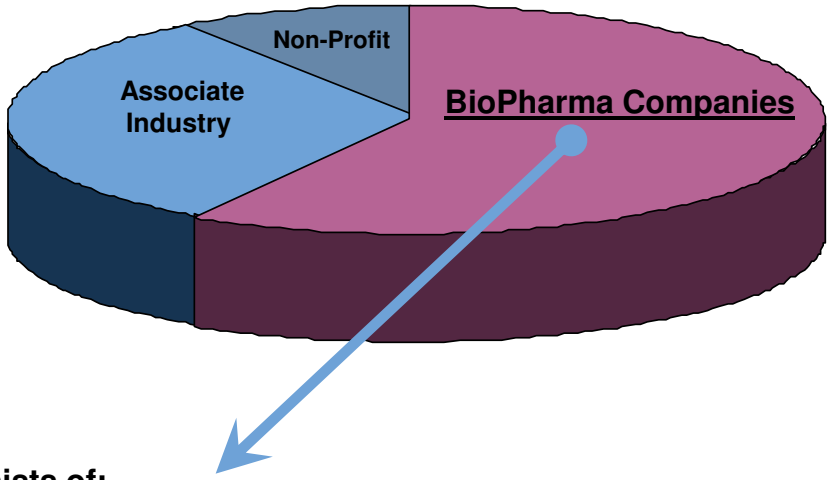
MassBioEd

# About MassBio

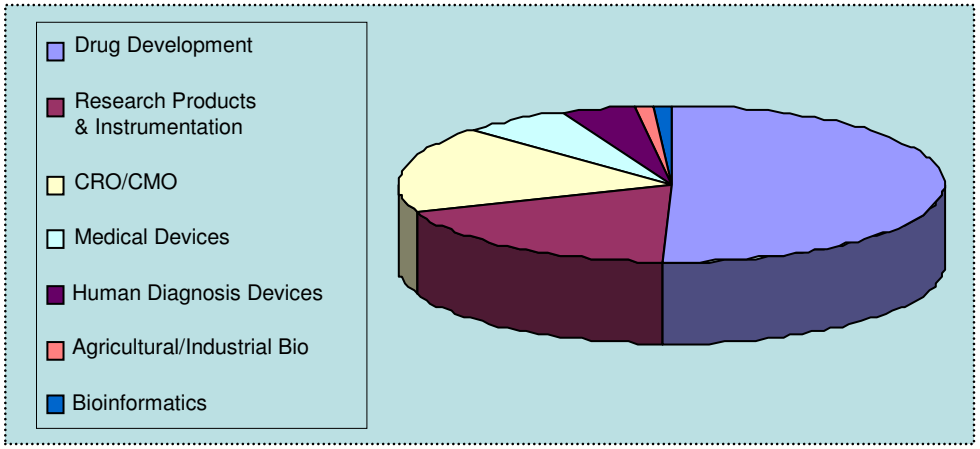
**600+ Total Members**

**400+ Biopharma Members**

**MassBio Member Types**

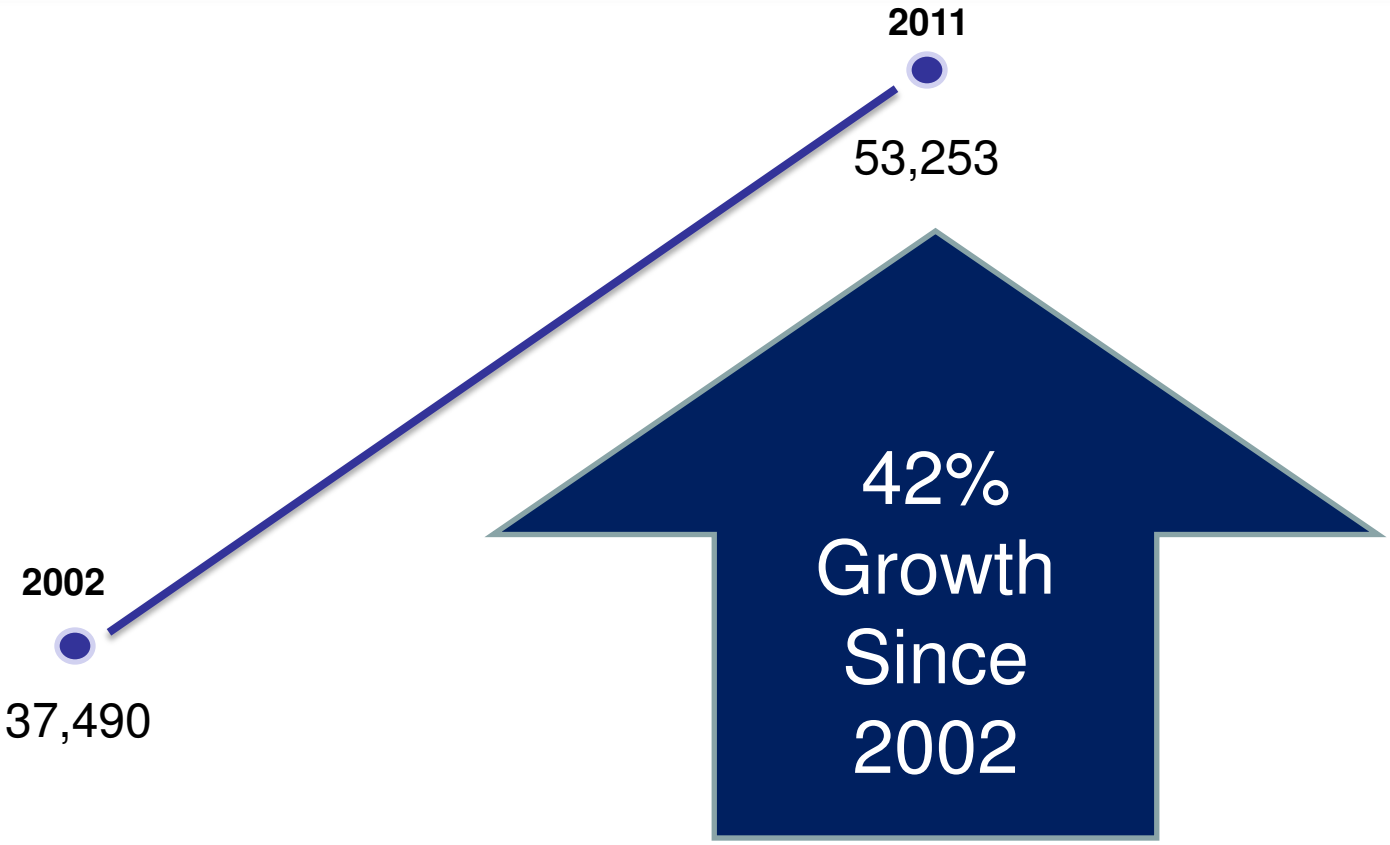



**The BioPharma membership category consists of:**



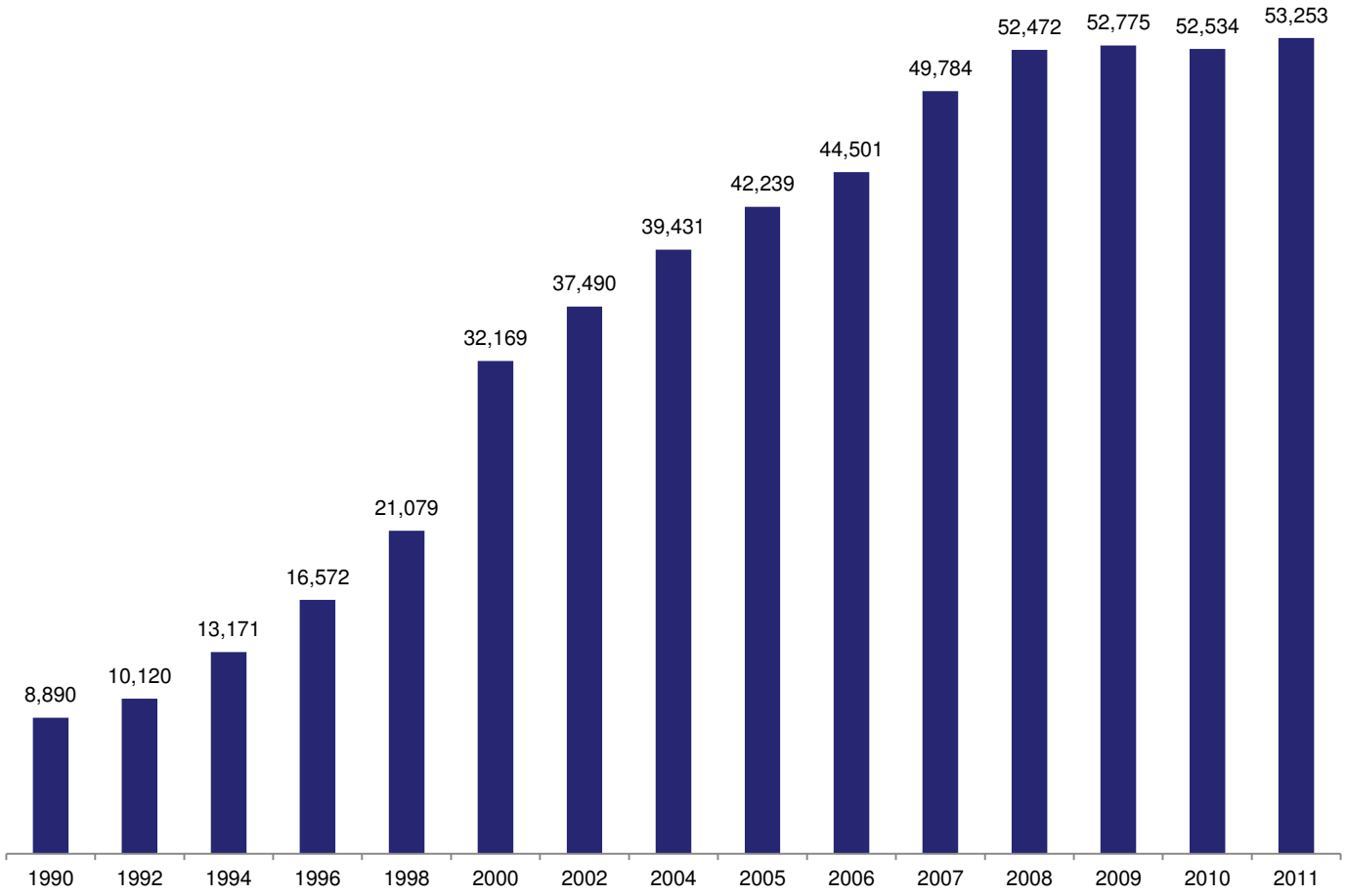
# MA BioPharma Employment Growth

The numbers for 2012 are not in yet, but we expect strong growth.




Source: U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages (QCEW)

# MA BioPharma Growth since 1990




Sources: U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages (QCEW), MassBio Annual reports 1994-1998.

# Biotechnology R&D Employment

According to the Bureau of Labor Statistics, Massachusetts leads the nation in biotechnology research & development employment (NAICS 541711).

| | 2007 | 2011 |
|---|---|---|
| CA | 19,134 | 22,592 |
| MD | 10,154 | 8,933 |
| MA | 24,656 | 28,177 |
| MO | 4,262 | 3,659 |
| NJ | 8,567 | 9,338 |
| NY | 2,679 | 3,677 |
| NC | 7,042 | 6,785 |
| OH | 2,696 | 3,098 |
| PA | 16,902 | 11,234 |
| TX | 4,229 | 4,299 |
| WA | 2,499 | 3,832 |

Source: U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages (QCEW)

# BioPharma Manufacturing

U.S. biopharma manufacturing employment has declined by **7.9%** since 2002.

Only a handful of states, including MA, ran counter to the trend.

**MFG Employment, 2011**

| | | |
|---|---|---|
| 1 | CA | 42,903 |
| 2 | NJ | 30,032 |
| 3 | NC | 20,395 |
| 4 | PA | 20,291 |
| 5 | NY | 19,587 |
| 6 | IL | 17,959 |
| 7 | PR | 15,239 |
| 8 | IN | 14,848 |
| 9 | TX | 9,595 |
| 10 | MA | 8,654 |
| 11 | MI | 7,643 |
| 12 | CT | 7,003 |
| 13 | MD | 6,874 |
| 14 | OH | 5,220 |
| 15 | MO | 4,637 |

Massachusetts is one of only 5 of the leading biopharma manufacturing states that grew employment since 2002.

**Growth/Decline since 2002**

| | | |
|---|---|---|
| CA | 3,003 | 7.5% |
| MD | 1,837 | 36.5% |
| OH | 943 | 22.0% |
| TX | 698 | 7.8% |
| MA | 360 | 4.3% |
| NC | -317 | -1.5% |
| MO | -321 | -6.5% |
| NY | -1,851 | -8.6% |
| IL | -3,027 | -14.4% |
| CT | -3,570 | -33.8% |
| MI | -4,279 | -35.9% |
| IN | -4,710 | -24.1% |
| PA | -6,830 | -25.2% |
| NJ | -9,345 | -23.7% |
| PR | -11,151 | -42.3% |
| **US** | -23,265 | -7.90% |

Source: U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages (QCEW)

# BioPharma Industry Impact in MA

The estimated average salary in the biopharma industry is 89.9% higher than the estimated state average salary of $59,676.

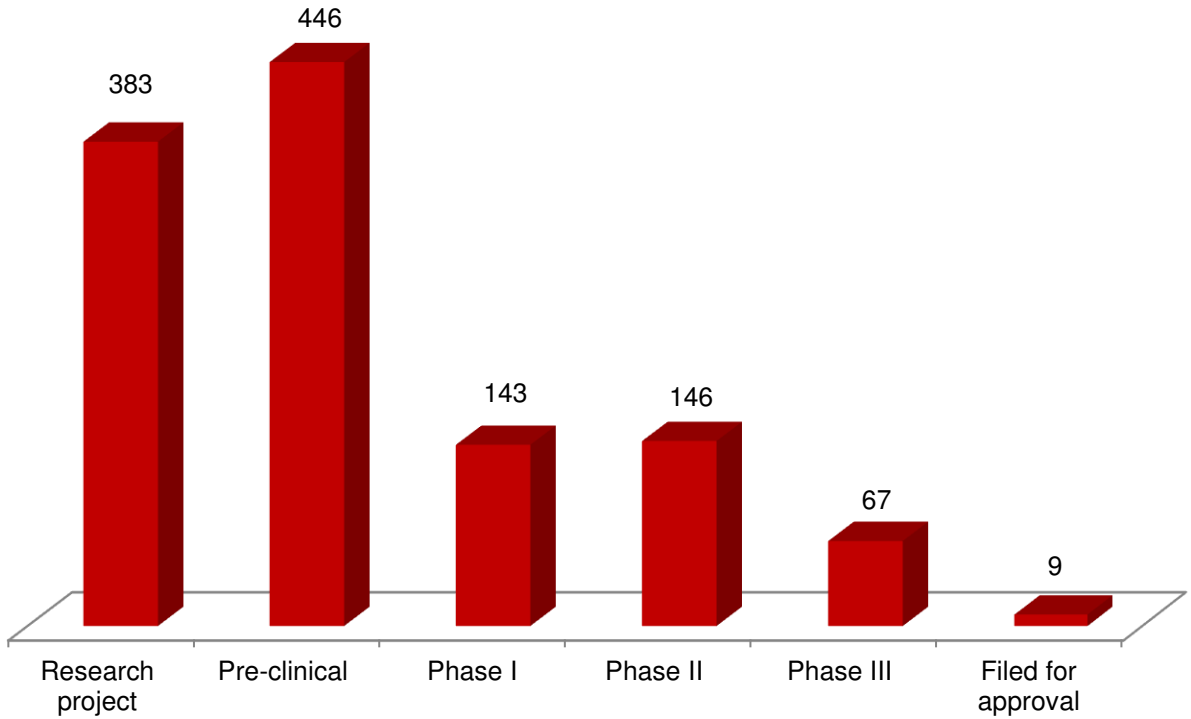
$6,036,942,570 in payroll (2011)

$113,364 in average salary (2011)

Source: U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages (QCEW)

# Drug Development Pipeline, March 2013

Candidate medicines of Massachusetts-headquartered* companies, by clinical trials stage

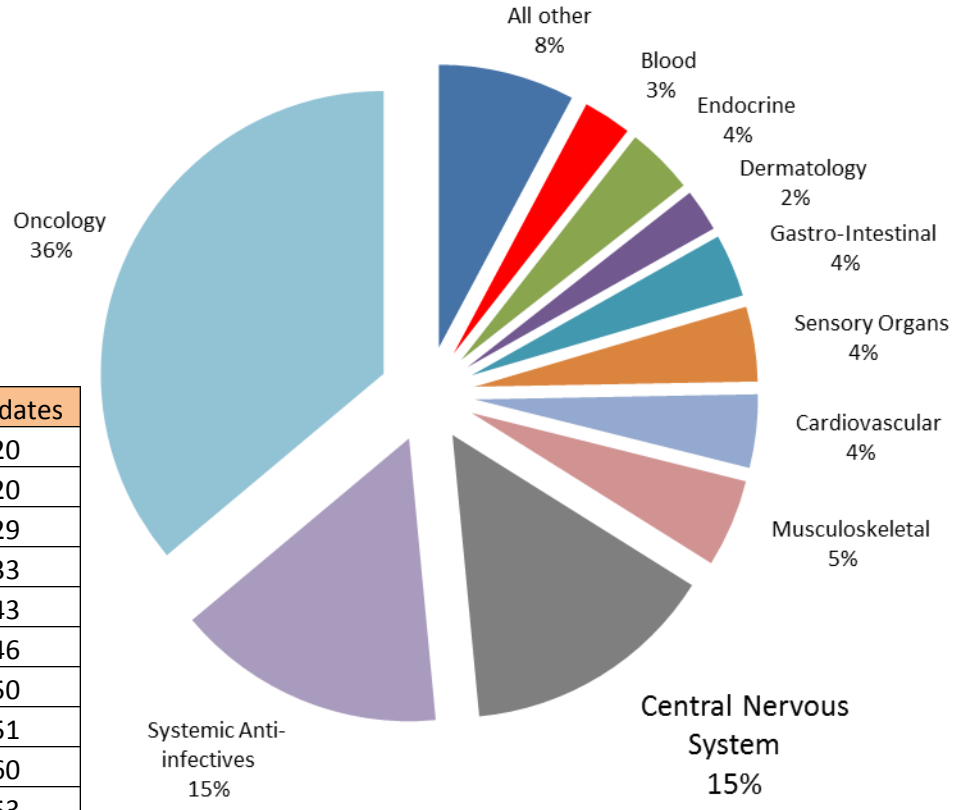



Massachusetts-headquartered companies* have a total of 1,194 drug candidates at some stage of R&D.

* There are many drugs in development in Massachusetts by companies with headquarters located outside of Massachusetts. These candidate drugs are not included in this report.

Source: EvaluatePharma®

# Massachusetts Pipeline by Therapeutic Area, 2013



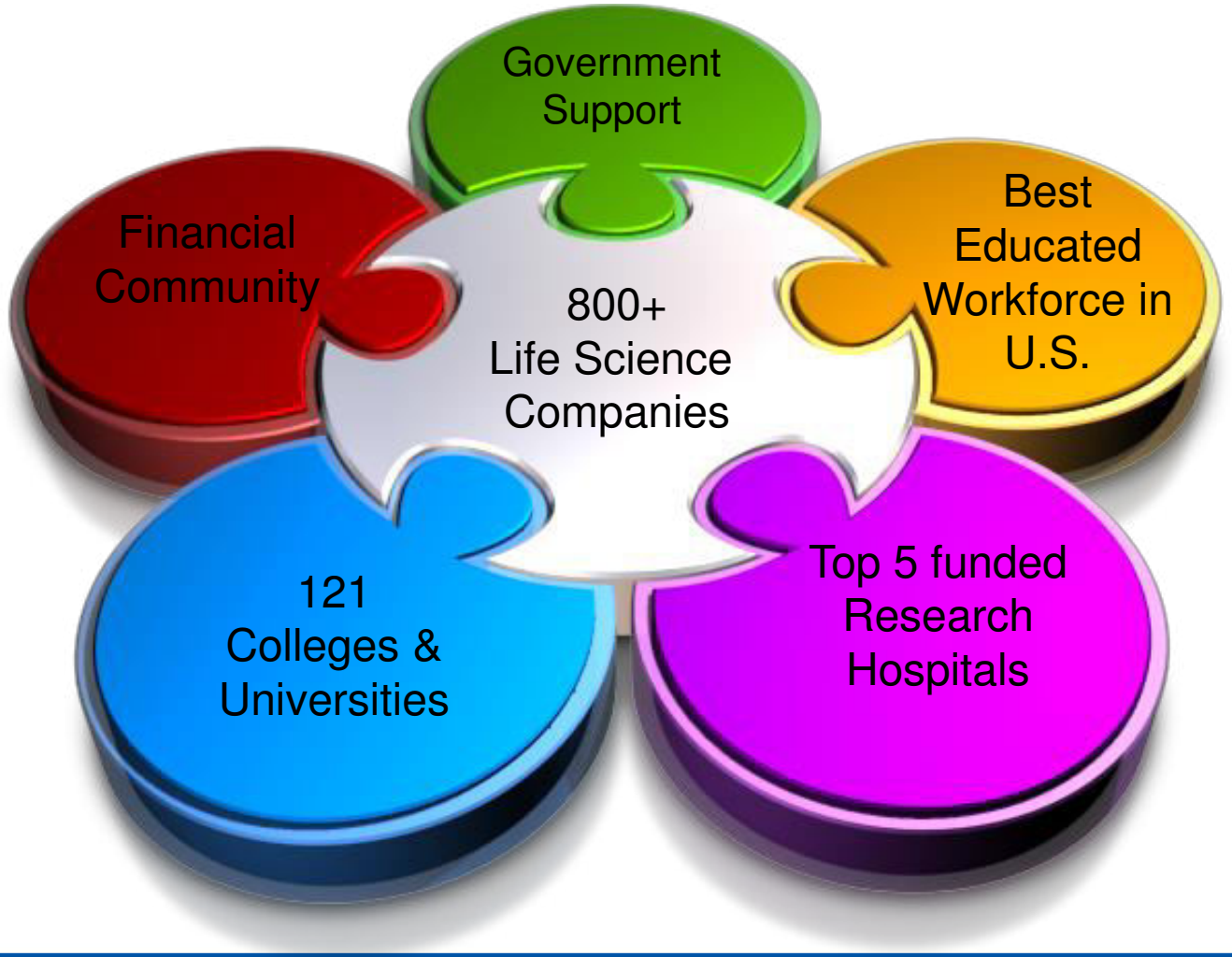

| Therapeutic Area | Candidates |
|---|---|
| Genito-Urinary | 20 |
| Respiratory | 20 |
| Dermatology | 29 |
| Blood | 33 |
| Gastro-Intestinal | 43 |
| Endocrine | 46 |
| Cardiovascular | 50 |
| Sensory Organs | 51 |
| Musculoskeletal | 60 |
| All Other | 53 |
| Central Nervous System | 174 |
| Systemic Anti-infectives | 184 |
| Oncology | 431 |
| Total (R&D) | 1194 |

Oncology accounts for 36% of Massachusetts' pipeline

Source: EvaluatePharma®

# Why Massachusetts?

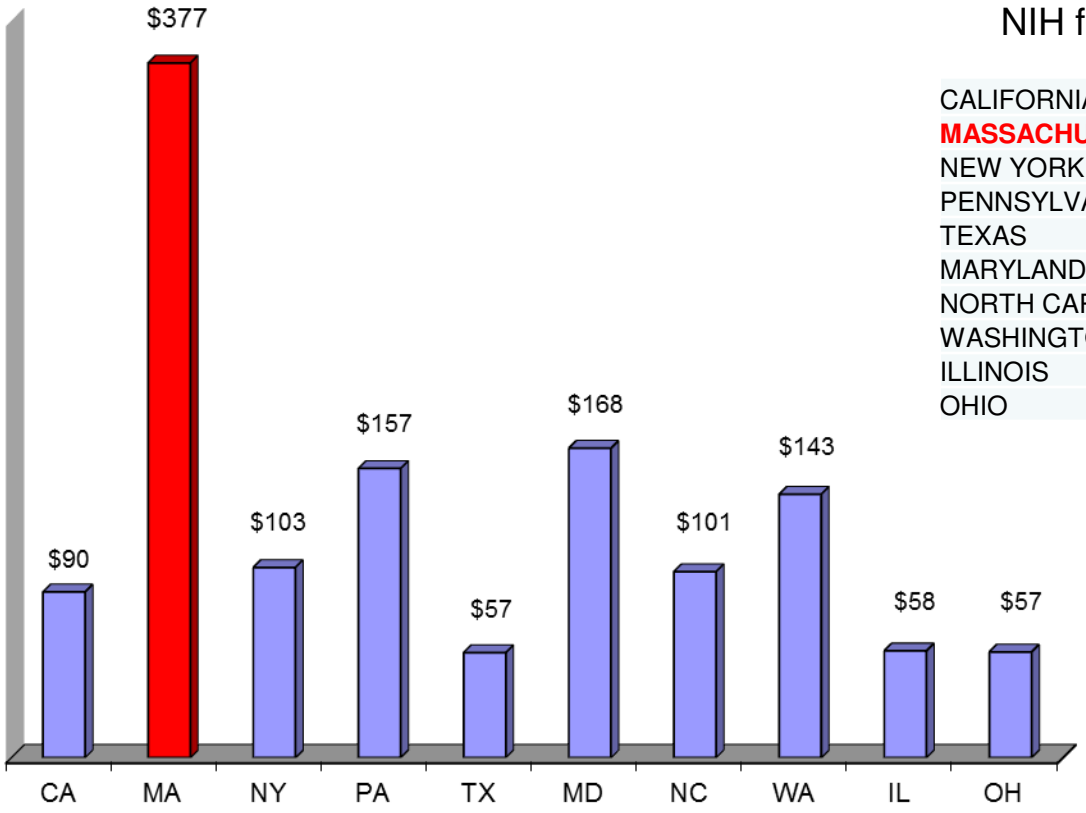
The industry grew in Massachusetts because the great concentration of universities, research hospitals, educated workers, and the presence of a strong investment community and entrepreneurs. In the last decade especially, state government has also provided innovative programs to support the industry.



# National Institutes of Health Funding, 2012

On a NIH-funding ***per capita basis***, Massachusetts far exceeded other leading NIH-recipient states.

NIH funding per capita, 2012




NIH funding by state

| | |
|---|---|
| CALIFORNIA | $3,334,766,795 |
| **MASSACHUSETTS** | **$2,471,024,302** |
| NEW YORK | $1,999,128,655 |
| PENNSYLVANIA | $1,432,321,696 |
| TEXAS | $1,042,115,177 |
| MARYLAND | $969,955,991 |
| NORTH CAROLINA | $964,422,526 |
| WASHINGTON | $858,955,675 |
| ILLINOIS | $746,312,120 |
| OHIO | $661,209,978 |

Sources: National Institutes of Health, Research Portfolio Online Reporting Tools and U.S. Census Bureau.

# Top 20 NIH-Funded Research Hospitals in U.S.

The top 5 NIH funded independent hospitals in the U.S. in 2012 are in Boston.

| ORGANIZATION | AWARDS | FUNDING |
|---|---|---|
| MASSACHUSETTS GENERAL HOSPITAL | 794 | $345,753,439 |
| BRIGHAM AND WOMEN'S HOSPITAL | 584 | $332,521,349 |
| BETH ISRAEL DEACONESS MEDICAL CENTER | 274 | $129,691,590 |
| DANA-FARBER CANCER INSTITUTE | 213 | $124,380,684 |
| CHILDREN'S HOSPITAL BOSTON | 302 | $122,338,322 |
| CHILDRENS HOSPITAL OF PHILADELPHIA | 218 | $119,467,054 |
| CHILDREN'S HOSPITAL MEDICAL CENTER CINCI | 249 | $101,839,995 |
| ST. JUDE CHILDREN'S RESEARCH HOSPITAL | 108 | $55,097,329 |
| NEW YORK STATE PSYCHIATRIC INSTITUTE | 114 | $49,807,571 |
| BOSTON MEDICAL CENTER | 92 | $37,309,152 |

# Top 20 NIH-Funded Institutions (non hospital)

The NIH is funding research being done throughout the Commonwealth, including at the UMass Medical School in Worcester, UMass Amherst.

| Institution | Funding | Grants |
|---|---|---|
| HARVARD UNIVERSITY (MEDICAL SCHOOL) | $200,413,466 | 355 |
| UNIV OF MASSACHUSETTS MED SCH WORCESTER | $153,534,616 | 339 |
| BOSTON UNIVERSITY MEDICAL CAMPUS | $132,434,111 | 237 |
| HARVARD UNIVERSITY (SCH OF PUBLIC HLTH) | $120,611,357 | 168 |
| BROAD INSTITUTE, INC. | $111,141,202 | 36 |
| MASSACHUSETTS INSTITUTE OF TECHNOLOGY | $106,816,552 | 248 |
| HARVARD UNIVERSITY | $66,900,244 | 131 |
| TUFTS UNIVERSITY - Boston | $46,917,990 | 124 |
| BOSTON UNIVERSITY | $44,971,719 | 117 |
| NORTHEASTERN UNIVERSITY | $24,625,609 | 53 |
| BRANDEIS UNIVERSITY | $24,393,136 | 78 |
| NEW ENGLAND RESEARCH INSTITUTES, INC. | $21,578,242 | 15 |
| JOSLIN DIABETES CENTER | $20,102,638 | 40 |
| MASSACHUSETTS EYE AND EAR INFIRMARY | $19,828,336 | 52 |
| WHITEHEAD INSTITUTE FOR BIOMEDICAL RES | $18,081,392 | 43 |
| UNIVERSITY OF MASSACHUSETTS AMHERST | $16,668,751 | 58 |
| IMMUNE DISEASE INSTITUTE, INC. | $13,767,584 | 23 |
| SCHEPENS EYE RESEARCH INSTITUTE | $12,598,826 | 27 |
| FORSYTH INSTITUTE | $11,749,061 | 22 |
| TUFTS UNIVERSITY MEDFORD | $8,783,831 | 30 |

Source: National Institutes of Health, Research Portfolio Online Reporting Tools

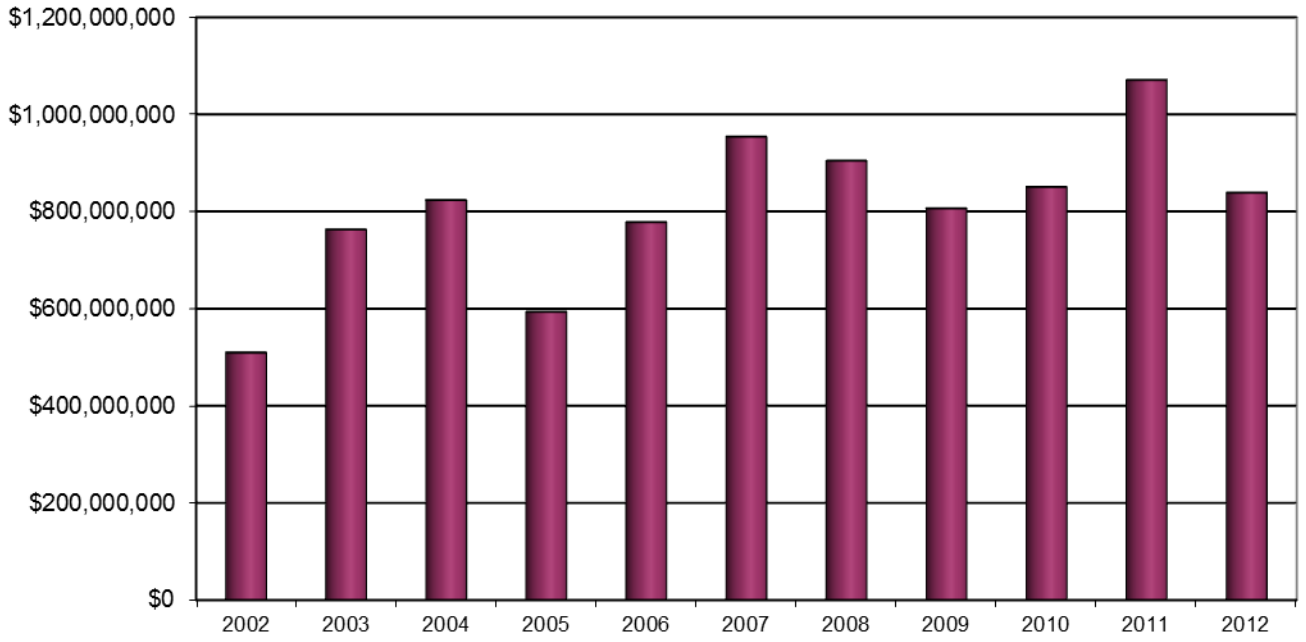
# Venture Capital Investment

Venture investment in MA biotechs declined from an all-time high in 2011 to: **$838 million** (national decline in VC biotech was 15% in 2012)

That makes **$8.892 billion** invested since 2002.

MA received **21%** of all U.S. biotech VC in 2012.

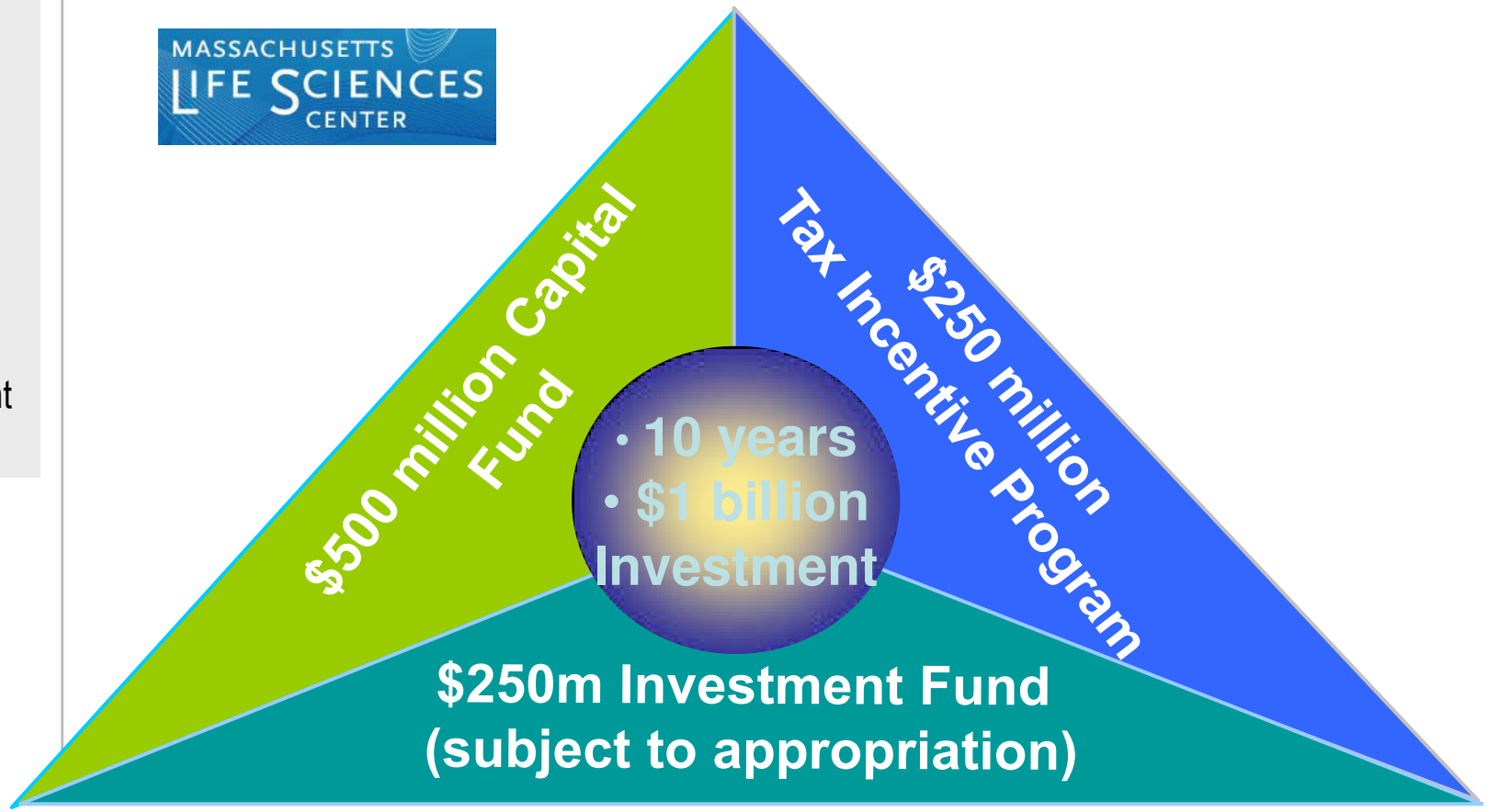
Investment in Massachusetts Biotech Companies, 2002-2012




Source Data: 2013 PricewaterhouseCoopers, National Venture Capital Association, MoneyTree™ Report, Historical Trend Data

# The $1 Billion Massachusetts Life Sciences Initiative

Over time, the industry demonstrated its value, commitment to the region, and promise for the future . . . and state government responded.



# Leading BioPharma Employers in MA

Of the leading 30 biopharma company employers in Massachusetts, 12 employ 1,000 or more workers.

| | | |
|---|---|---|
| 1 | Genzyme, a Sanofi Company | 4,356 |
| 2 | Pfizer | 2,600 |
| 3 | Biogen Idec | 2,100 |
| | Novartis | 2,100 |
| 5 | Shire | 1,500 |
| 6 | Thermo Fisher Scientific | 1,450 |
| 7 | EMD Millipore | 1,356 |
| 8 | Vertex | 1,342 |
| 9 | Parexel International | 1,200 |
| | Hologic | 1,200 |
| 11 | Millennium: Takeda Oncology | 1,144 |
| 12 | AstraZeneca | 1,000 |
| 13 | Charles River Laboratories | 870 |
| 14 | EMD Serono | 854 |
| 15 | Abbott Laboratories | 775 |

| | | |
|---|---|---|
| 16 | Sunovion Pharmaceuticals (DSP) | 699 |
| 17 | Cubist | 638 |
| 18 | Nova Biomedical | 630 |
| 19 | Lantheus | 500 |
| | Merck | 500 |
| 21 | Bristol-Myers Squibb | 320 |
| 22 | Alkermes | 300 |
| | Athena Diagnostics | 300 |
| 24 | New England Biolabs | 280 |
| 25 | Eisai | 279 |
| 26 | Organogenesis | 274 |
| 27 | Cell Signaling | 270 |
| 28 | Ironwood | 260 |
| 29 | Immunogen | 247 |
| 30 | Merrimack | 210 |

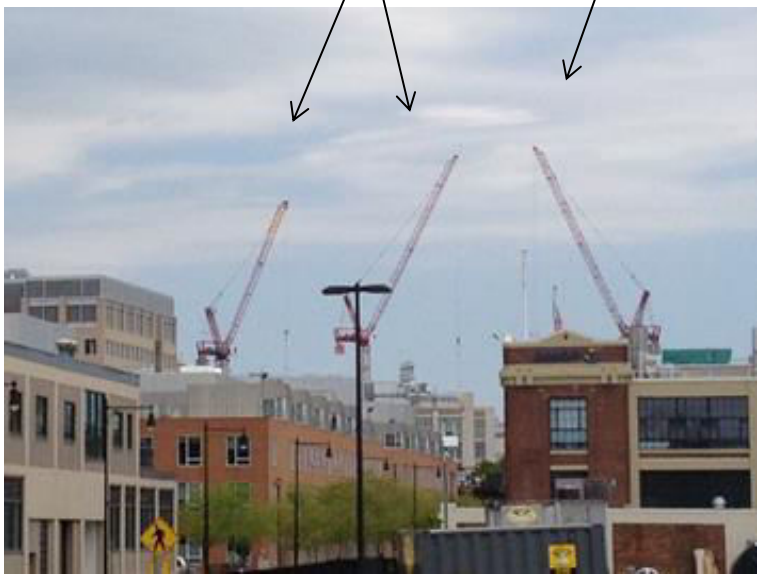
Sources: MassBio, membership reports, survey and Boston Business Journal Book of Lists, 2012.

# The Cranes are Back

The Broad Institute

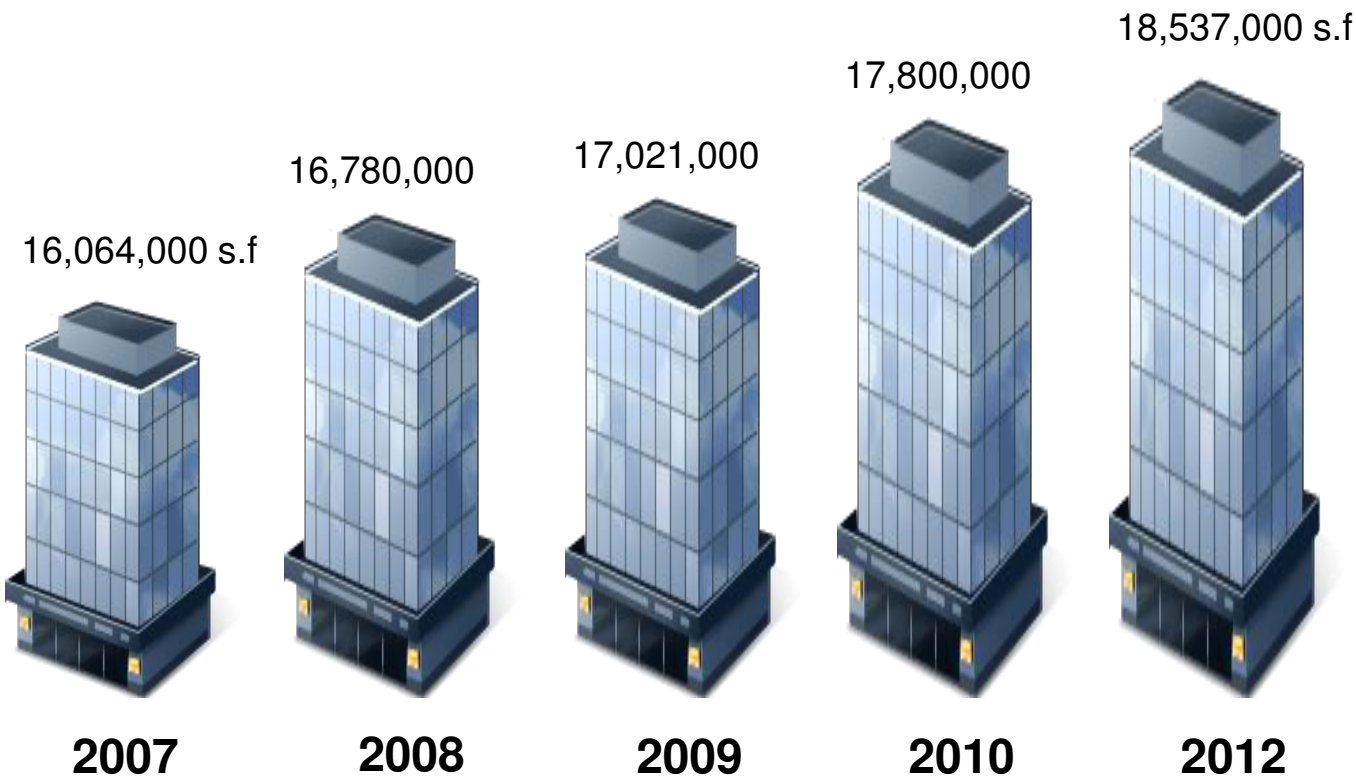
Novartis

Pfizer



# Life Sciences Lab Inventory Growth

**2.2 million s.f.** of commercial laboratory space is currently under construction, including Biogen Idec, Pfizer, Novartis, and Vertex.




Source: Colliers Meredith & Grew, Life Science Review, 2007-2011

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## Worcester/I-495

60+ biotech companies, WPI, UMass-Worcester, and 16 other colleges

abbvie · Sunovion · Bristol-Myers Squibb · Lonza · genzyme

## Northeast

100+ biotech companies, 2 million+ s.f. in lab space, UMass-Lowell and 11 other colleges

Pfizer · Eisai · BioLabs · Charles River Laboratories · Cell Signaling Technology

## Boston-Cambridge Core

180+ biotech companies, the top 5 NIH-funded hospitals in the U.S., and 48 colleges.

biogen idec · Sanofi · Vertex · Novartis · genzyme


Home of the University of Massachusetts-Amherst and 21 other colleges. Area known as The Knowledge Corridor.

Microtest · Nuclea Biotechnologies

## The West

The immediate western suburbs include 70+ biotech companies, 15 colleges, 3 million s.f. of lab space

AstraZeneca · ThermoFisher Scientific · Cubist · Shire · AMAG

## 128/Suburbs

Strong med device and biopharma manufacturing capacity, with numerous BioReady™ land sites and 10 colleges..

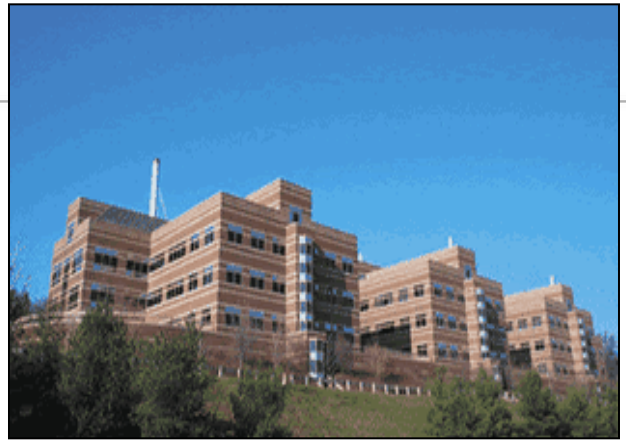
EMD Serono · Celldex · Associates of Cape Cod · SeraCare Life Sciences

## Metro South, SouthCoast, South Shore &Cape

# Biotech/pharma Buildings

Pfizer, Andover

EMD Millipore Corp., Bedford, MA.



Abbvie, Worcester, MA

Bristol Myers Squibb, Devens

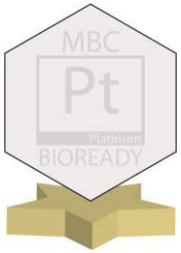
AstraZeneca R&D Boston, Waltham, MA

# Massachusetts BioReady™ Community Ratings


**Bronze** - A municipality at this level features municipal water and sewer in commercial and industrial areas, zoning allowing for biotech laboratory and manufacturing uses by *special permit*, and has identified a local point of contact in to assist biotech projects.


**Silver** - A municipality meets all Bronze criteria AND allows biotech uses *by right*, convene Site Plan Review meetings to expedite development projects, and has identified sites for biotech uses in municipal plans or has land sites and/or buildings included in BioSites inventory at www.massachusettssitefinder.com*, or* is a Growth District*, or* has identified Priority Development Sites per Chapter 43D.


**Gold** - A municipality meets Silver criteria *plus* has sites or buildings pre-permitted for biotechnology use, *OR* has existing buildings in which biotech laboratory or manufacturing activities are taking place.




**Platinum** - A municipality meets Gold criteria *plus* has adopted the National Institutes of Health guidelines on rDNA activity as part of its Board of Health regulations, has a building or buildings that are already permitted for biotech uses and which have 20,000+ square feet available space for biotech uses *OR* has a shovel-ready pre-permitted land site with completed MEPA review and municipal water and sewer capacity to meet additional demand.

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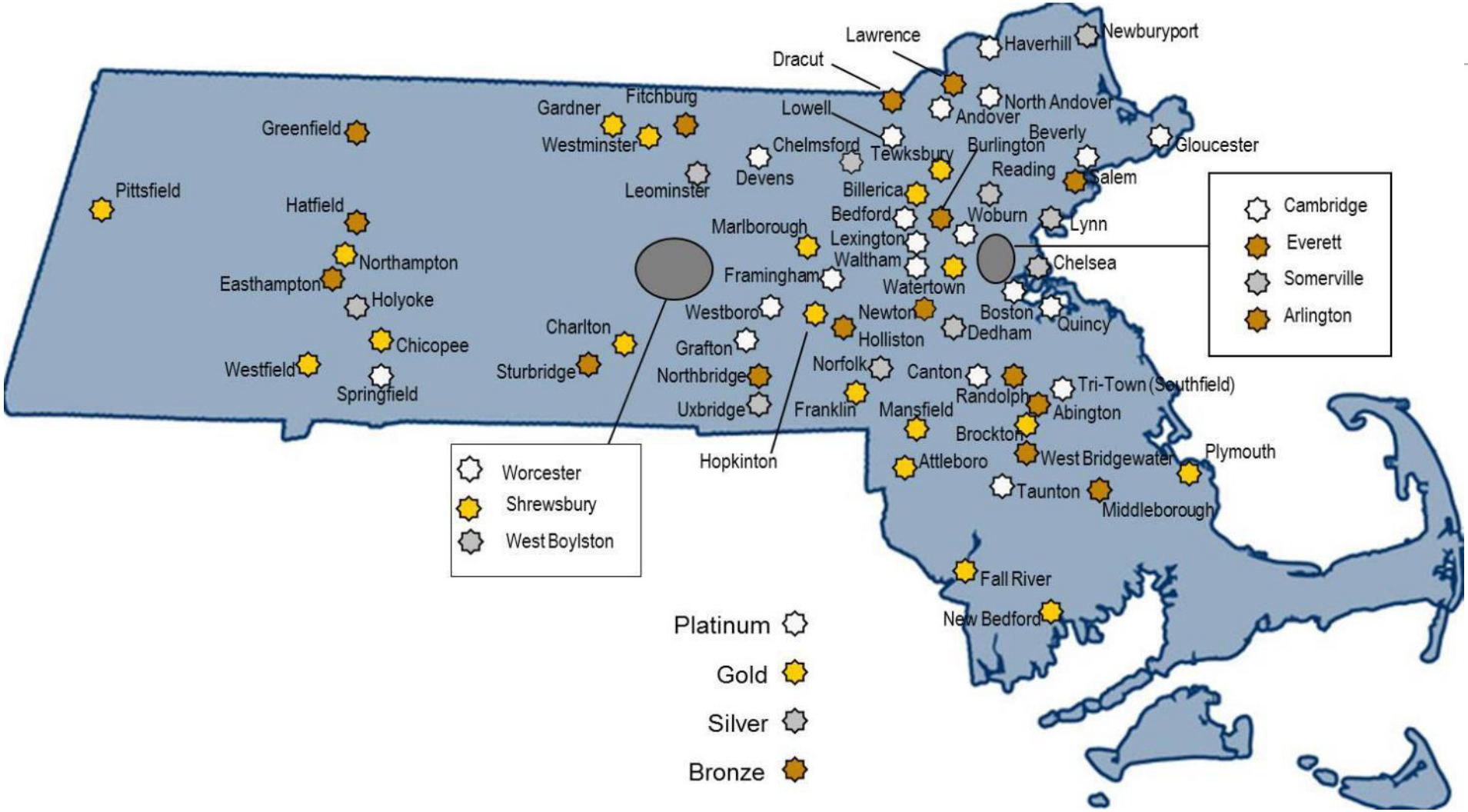
## (November 2012)



# Westminster is Gold

Westminster has three 43D Priority Development Sites listed with the State: 1) Westminster Business Park 2) Simplex Drive and 3) Fitchburg Road. All three are located within industrial zoning districts, which means that biotechnology laboratories and pharmaceutical manufacturing are uses allowed By Right. The Westminster Business Park (WBP) consists of fully permitted plans for the eventual construction of 1.57 million square feet of new industrial space on 312 acres of land. Also, 100 Simplex Drive currently has 385,000 square feet of available space for lease.

100 Simplex Drive has 385,000 square feet of floor space available for lease RIGHT NOW. This 43D Priority Development site is entirely within an industrial zoning district which allows biotechnology laboratories and pharmaceutical manufacturing By Right.

# Biotechnology R&D Employment (NAICS 541711)

| | 2008 | 2010 |
|---|---|---|
| Middlesex, MA | 16,481 | 17,090 |
| San Diego, CA | 7,903 | 8,802 |
| Montgomery, PA | 9,971 | 8,484 |
| Montgomery, MD | 5,451 | 5,214 |
| Suffolk, MA | 4,916 | 4,902 |
| San Mateo, CA | 3,466 | 2,957 |
| Santa Clara | 4,101 | 2,826 |
| Essex, MA | 2,642 | 2,447 |
| St. Louis, MO | 2,596 | 2,408 |
| Chester, PA | 2,531 | 2,298 |
| Durham, NC | 2,285 | 2,223 |
| Somerset, NJ | 1,813 | 1,840 |
| Middlesex, NJ | 1,452 | 1,739 |
| Mercer, NJ | 2,100 | 1,643 |
| Wake, NC | 2,028 | 1,252 |
| Worcester, MA | 1,121 | 1,248 |

Source: U.S. Bureau of Labor Statistics, QCEW

2011: 1,842 R&D + 701 BioPharma MFG = 2,543

# NIH Funding, 2012

## Top Massachusetts NIH recipient universities

| | | |
|---|---|---|
| HARVARD UNIVERSITY (MEDICAL SCHOOL) | 378 | $202,633,266 |
| UNIV OF MASSACHUSETTS MED SCH WORCESTER | 308 | $134,169,972 |
| BOSTON UNIVERSITY MEDICAL CAMPUS | 241 | $116,030,729 |
| MASSACHUSETTS INSTITUTE OF TECHNOLOGY | 245 | $102,189,956 |
| HARVARD UNIVERSITY | 128 | $63,606,016 |
| TUFTS UNIVERSITY BOSTON | 133 | $47,530,653 |

Sources: National Institutes of Health, Research Portfolio Online Reporting Tools and U.S. Census Bureau.

# Thank You

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# Appendix

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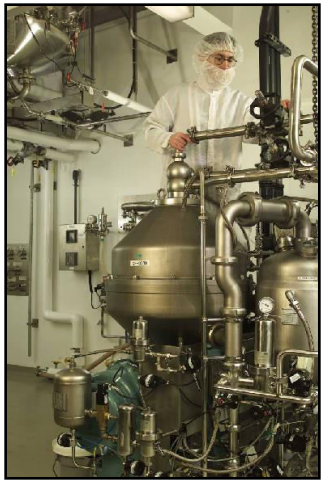
## Biotechnology *Laboratory* Facilities




## Biotechnology *Manufacturing* Facilities

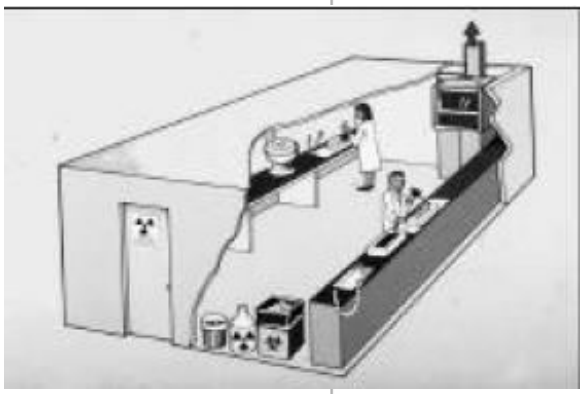





# *Laboratory Safety*

## BioSafety Level 1

Suitable for work involving well characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.



## BioSafety Level 2

Suitable for work involving agents of moderate potential hazard to personnel and the environment.

## BioSafety Level 3

Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

Source: Centers for Disease Control

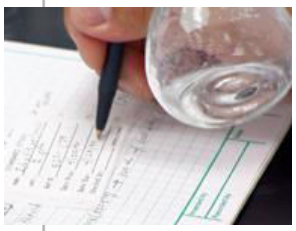
# Manufacturing Safety

Good Manufacturing Practice regulations (GMPs) are used by pharmaceutical and medical device manufacturers as they produce and test products that people use. In the United States, the U.S. Food and Drug Administration (FDA) has issued these regulations as the minimum requirements.

- Human pharmaceutical products and veterinary products (21 CFR 210-211)
- Biologically derived products (21 CFR 600 and 21 CFR 620)
- Medical devices (21 CFR 820)

The manufacturing or "production" area is where the drug products are actually made with the active pharmaceutical ingredients and other materials such as high-purity water or sugars and other binding/lubricating agents. Depending on the final product, the manufacturing process can be very simple or extremely complicated.

Facilities
Control Room



Labeling in Laboratory

Laboratory Instrumentation

Quality assurance

Quality Control

Validation

**Source: Learning Plus, Inc.**

# Snapshot of Lab & Plant Physical Requirements

| | Hours of Operation | Floor to Floor heights | Electrical | Water | Sewer | Gas |
|---|---|---|---|---|---|---|
| Basic Research Facility | Typical business hours | 14-18' | 12 KV | 8-20,000 GPD | Some pretreatment, use of neutralization tanks | Required |
| Process Development Facility | Typical business hours | 14-18' | 12 KV | 20,000 GDP | Pretreatment using neutralization tanks | Required |
| Pilot Manufacturing | 24 hours a day, 7 days a week | 18-25' | 15 KV | 2,400 GPH per 1,000 s.f. (approx. 60,000 GPD for 30 K s.f. facility) | Adequate public sewer capacity. Discharges require kill syetems and pH pretreatment | Higher volume than research or process facilities. |
| Manufacturing | 24 hours a day, 7 days a week | 20-40' | 25 KV with redundant supply | Varies, greater than Pilot facility, redundent supply often required. (1.5 M GPD for 100 k mfg space an example) | Adequate public sewer capacity. Discharges require kill syetems and pH pretreatment | High volume |
| Fill and Finish Facility | 5 days of operation, 24/7 on utilities | 25' minimum | 12.5 KV | Varies, but significantly less than mfg. facility | | Required |